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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,152	02/17/2004	Andreas Hefel	RBL0109	1277

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EXAMINER	
MAEWALL, SNIGDHA	
ART UNIT	PAPER NUMBER
1612	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/780,152	HEFEL, ANDREAS	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *21,23,24,26,28,29,32,34 and 35* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *21, 23-24, 26, 28-29, 32, 34-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Summary

1. Receipt of Applicant's Arguments/Remarks and amended claims filed on 01/04/10 is acknowledged.

Claims 1-20, 22, 25, 27, 30-31 and 33 have been cancelled in this Application.

Claims 21, 24, 28, 34 and 35 have been amended.

Accordingly, claims **21, 23-24, 26, 28-29, 32 and 34-35** are under prosecution.

The rejections made under 35 USC 112.2 have been withdrawn in light of claim amendments and applicant's arguments.

The following rejections are maintained for reasons of record set forth in the Office Action mailed out on 09/01/09, repeated below, slightly altered to take into consideration Applicant's amendment filed on 01/04/10.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

3. Claims 21, 23, 26, 28-29, 32 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata (EP 835654 A1).

Shibata teaches a method of producing a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient, the method comprising admixing a predetermined amount of said pharmacologically active ingredient with a predetermined amount of glucomannan (claim 4). The reference discloses that glucomannan makes a very viscous solution when dissolved in water and that glucomannan is not decomposed in the small intestine but is decomposed in the large intestine by Escherichia coli and loses its viscosity. The reference discloses the possibility of properly delaying absorption of a drug in the small intestine both by suppressing conveyance of the drug though the small intestine in the direction to the anus and suppressing diffusion of the drug in the solution (thus slowly released for resorption by the human or animal digestive system), both making use of the viscosity of the solution. As a result, the inventor has found that when glucomannan is orally administered together with a drug, gradual absorption of the drug occurred over a prolonged time period (thus increase of the nutrient-bio-availability of vital substances) compared with the case without administration of glucomannan, and that there is no reduction of overall absorption of the drug (thus separated from each other in their function) (page 2, lines 28-38). Thus, the present invention provides a pharmaceutical preparation with sustained effect for oral administration of a pharmacologically active ingredient comprising a mixture of said pharmacologically active ingredient and glucomannan (thus increase for improvement of wellbeing) (thus the embedded active substances are slowly released for resorption). In accordance with the present invention, the length of time during which the absorption of the pharmacologically active

ingredient takes place may be conveniently controlled by simply adjusting the proportion of glucomannan to the amount of the active ingredient. Thus, the present invention allows sustainment of pharmacological effect of a variety of active ingredients orally administered to mammals including human (page 2, lines 38-44). Shibata further teaches the pharmaceutical preparation may be in any convenient form suitable to oral administration, such as a powder, granules, capsules, tablets, an aqueous preparation (page 3, lines 20-22).

It is to be noted that claims 26 and 28 provide the functional limitations once the active substance is introduced into human or animal, since the claimed compound is similar to the compound disclosed in the prior art, the functional limitations are considered to be associated with process.

The reference discloses that it is possible to combine two or more active ingredients with similar or different activities, see page 3, lines 18-20. The preparation also includes gel type preparation, it may be possible to add excipients and coloring material and binders for granules, see page 3, lines 20-25. Regarding the limitations the active substance is bound within the interstices of he lattice structure, it is the position of the examiner that since same glucomannan is taught in prior art and introduction of active substance is also taught in prior art, the positioning of active substance in lattice structure will be same as claimed.

Based on the teachings of the prior art, it would have been within the purview of a skilled artisan to formulate a process of providing a human or animal a composition comprising two active ingredients which are functionally separated having none

antagonistic interactions as taught by Shibata because Shibata teaches that it is possible to combine two or more active ingredients in the composition. Shibata also suggests making granules by adding excipients; as such it would have been with in the purview of skilled artisan to make a matrix comprising an active ingredient embedded in matrix of glucomannan for increased absorption when administered orally to humans. Since the reference discloses use of the composition in delaying absorption of a drug in the small intestine both by suppressing conveyance of the drug though the small intestine in the direction to the anus and suppressing diffusion of the drug in the solution due to the viscosity parameters of the composition, one of ordinary skill in the art would have envisaged embedding one or more active ingredients separately in glucomannan and providing the same to human in order to avoid any antagonistic interaction between the two compositions.

4. Claims 21, 23-24, 26, 28-29, 32 and 34-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata (EP 835654 A1) in view of Walter (GB 2257358 A, presented in IDS) or vice versa.

The teachings of Shibata have been discussed above. Shibata suggests making granules of the composition but does not teach the process of making the composition.

Shibata does not specifically disclose providing first and second composition, although the reference suggests that more than one active can be included in the composition.

Walter discloses a composition comprising vitamins, enzymes, coenzymes, minerals, trace elements and/or microorganisms that are embedded, separately with regard to function in carrier substances with formation of protective films against harmful effects so that, with sufficient moisture absorption, **in vivo and in vitro biocatalytic processes can be initiated and controlled**. Suitable protective substances are preferably sodium salts and potassium salts of silicic acid and nonionic polysaccharides, in particular from the family consisting of the galactomannans (page 2, Paragraph 2 and **claim 5**).

The process of mixing and drying is depicted on page 4, paragraph 4, page 7, paragraph 1 and example 2). It is further disclosed that the **granulation** can be influenced by the spraying rate and the enzyme powders are obtained in a relatively narrow particle size ranges after drying (page 8, paragraph 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to utilize the process of making a composition comprising active ingredient embedded in glucomannan which are functionally separated from each other as taught by Walter in the teachings of Shibata because Walter teaches that such composition helps in controlled biocatalytic processes. One of ordinary skill would have been motivated to do so because Shibata teaches oral administration of composition comprising active ingredient in glucomannan for controlled and gradual absorption of the drug over a prolonged time period and Walter teaches process of making such composition comprising active ingredient embedded in glucomannan.

It would have been obvious to one of ordinary skill in the art at the time of instant invention to formulate two compositions independently comprising similar or different active ingredients embedded in glucomannan as taught by Walter because Walter teaches that such preparation provides functionally separated compositions with controlled in-vivo bioactive processes once administered. Since Shibata suggests including one or more active preparations in glucomannan and Walter teaches method of making such preparation, one of ordinary skilled in the art would have had reasonable expectation of success in preparing and administering to humans, first and second active agents functionally separated due to glucomannan with no antagonistic interactions.

Response to Arguments

5. Applicant's arguments filed 01/04/10 have been fully considered but they are not persuasive.

Applicant argues that Shibata states that, "it is possible to combine, two or more ....", teaching that different ingredients can be mixed together in its formulation not kept separate from one another as disclosed by the applicants. Far from making the applicants invention obvious, Shibata teaches away from the applicant's invention.

Applicant's arguments are not persuasive. Since Shibata teaches when glucomannan is orally administered together with a drug, gradual absorption of the drug occurred over a prolonged time period (thus increase of the nutrient-bio-availability of vital substances) compared with the case without administration of glucomannan, and

that there is no reduction of overall absorption of the drug, thus it is implied that it is always separated from each other in their functions.

Applicant further argues that there is no prevention of interaction between active substances being addressed or even suggested by the cited reference. The only problem being addressed is inactivation of enzymes and the like during industrial processing. Hence, mixing of active ingredients prior to processing with polysaccharides was perfectly acceptable according to the cited reference. The active ingredients are mixed in the first step and are then embedded in a second step. The premixing of the active ingredients taught by Walters and clearly consistent with the teaching of Shibata would obviate the applicant's invention. In so far as combining Shibata and Waiters, it would not have been obvious to one of ordinary skill in the art as Shibata teaches away from formulating active ingredients in a manner that prevents them from interacting with each other and their controlled release into the blood stream of a human or animal. Accordingly, the differences in the manufacturing processes and the implications for the subsequent uses of the granules as claimed by the applicants were simply not in, or apparent from, or obvious derivatives or combination of the cited art.

Applicant's arguments are not persuasive for the same reasons as above. Since Shibata teaches when glucomannan is orally administered together with a drug, gradual absorption of the drug occurred over a prolonged time period (thus increase of the nutrient-bio-availability of vital substances) compared with the case without administration of glucomannan, and that there is no reduction of overall absorption of the drug, thus it is implied that it is always separated from each other in their functions.

6. THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is (571)-272-6197. The examiner can normally be reached on Monday to Friday; 8:30 a.m. to 5:00 p.m. EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-0580. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status

information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Snigdha Maewall/

Examiner, Art Unit 1612

/Gollamudi S Kishore/

Primary Examiner, Art Unit 1612